

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 99N-1168]

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~~DEPARTMENT OF AGRICULTURE~~

~~Food Safety and Inspection Service~~

~~[Docket No. 00-048N]~~

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Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS, and Food Safety and Inspection Service, USDA.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA), in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), and the Centers for Disease Control and Prevention, published a notice of availability of a draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health and a proposed risk management action plan for *L. monocytogenes* in the **Federal Register** of January 19, 2001 (66 FR 5515). Interested persons were given until March 20, 2001, with an extension to May 21, 2001 (66 FR 13545), to comment on these documents. The LM Working Group has requested a second extension of the comment period in part to collect and review new data and to evaluate the model and the appropriateness of the new data to improve the assessment. In response, FDA and USDA/FSIS are extending the comment period to July 18, 2001; however, the agencies do not anticipate further extensions of the comment period for these draft documents.

DATES: Submit written comments by July 18, 2001.

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ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Docket No. 99N-1168, Food and Drug Administration, 5630 Fishers Lane, rm. 1060, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Received comments may be reviewed at the FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 00-048N, U.S. Department of Agriculture, Food Safety and Inspection Service, rm. 102, Cotton Annex, 300 12th St, SW., Washington, DC 20250-3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

For information concerning the draft risk assessment document: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS-032), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-3984, FAX 202-260-9653, e-mail: sdennis@cfsan.fda.gov.

For information concerning the risk management action plan: Kathy Gombas, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4231, FAX 202-260-0136, e-mail: kgombas@cfsan.fda.gov or Charles Edwards, Food Safety and Inspection Service, U.S. Department of Agriculture, rm. 405, Cotton Annex, 300 12th St. SW., Washington, DC 20250-3700, 202-205-0675, FAX 202-205-0080.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 2001 (66 FR 5515), the Department of Health and Human Services and USDA announced the availability of two documents: A draft risk assessment on the relationship between foodborne *L. monocytogenes* and human health and a draft risk management action plan. Comments were sought on the technical aspects of the draft risk assessment in the following areas: (1) The assumptions made, (2) the

modeling technique, (3) the data used, and (4) the transparency of the draft risk assessment document. The agencies also invited comments on the risk management strategies as presented in the draft action plan. Interested persons were given until March 20, 2001, to comment on the draft risk assessment and draft action plan. FDA and USDA/FSIS extended the comment period to May 21, 2001 (66 FR 13545, March 6, 2001), in response to the requests of the National Food Processors Association and the LM Working Group and because a public meeting to receive comments on these documents was scheduled on March 19, 2001, only 1 day before the close of the comment period. The LM Working Group has requested a second extension of the comment period in part to allow time to: (1) Collect and review new data, and (2) evaluate the model and the appropriateness of the new data to improve the assessment. In response, FDA and USDA/FSIS are extending the comment period to July 18, 2001; however, the agencies do not anticipate further extensions of the comment period for these draft documents.

To be considered, submit written comments to FDA Dockets Management Branch or the FSIS Dockets Clerk (addresses above) by July 18, 2001.

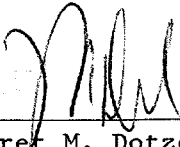
Printed copies of the draft risk assessment and the risk management action plan and/or a CD-ROM of the risk assessment model may be requested by faxing your name and mailing address with the names of the documents you are requesting to the CFSAN Outreach and Information Center at 1-877-366-3322. The documents may be reviewed at the FDA Dockets Management Branch or the FSIS Docket Clerk's Office at the addresses and hours noted above. The draft risk assessment and action plan documents are also available electronically as follows:

www.cfsan.fda.gov, www.fsis.usda.gov, www.foodsafety.gov.

Dated: 5/18/01

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May 18, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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